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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,185	12/29/2000	Nicholas Hunt	P66036US1	5831

7590

10/02/2002

JACOBSON, PRICE, HOLMAN & STERN
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EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,185

Applicant(s)

HUNT, NICHOLAS

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-236 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 119-236 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Preliminary amendment has been noted. Claims 1-118 have been canceled. Claims 119-236 have been added and are pending.

Claims 119-236 are very confusing and unclear because they appear to be a literal translation into English from a foreign document, which does not conform to the current U.S. practice.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 119-134 and 235-236, drawn to a method of encapsulating a proteineous target molecule into a viral like particle, classified as class 435, subclass 472 (1st product and a method of use).
 - II. Claims 119-133 and 135, drawn to a kit comprising the product and a method for making the product, classified as class 435, subclass 975 (2nd product and a method of use).
 - III. Claims 119-133 and 136--137, drawn to a method for making and using the product as a medicament, classified as class 424, subclass 9.2 (3rd product and a method of use).

The groups I-III are directed to the following patentably distinct species. If any one of groups from I-III is elected, Applicants are further required to selected one of the following species:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 119 is generic.

- A. The mechanism for using the first amino acid to make the product should be selected from: 1. Van der Waals forces, 2. Electrostatic forces, 3. Stacking interactions, 4. Hydrogen bonding, and 5. Steric fit.

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- B. The mechanism for releasing the viral like particle should be selected from: i. Exocytosis, ii. Lysis and iii. budding through the membrane.
 - C. The second amino acid sequence of target molecule should be selected from: a. A receptor, b. A iron channels, c. An enzymes, d. An adhesion molecule, e. A component of membrane pore and f) A luminescent peptide or protein.
 - D. The second amino acid sequence of signal molecule should be selected from: 1a. A viral capsid protein, 1b. A precursor of a viral capsid protein, 1c. A fragment of envelope protein, 1d. A precursor of a viral envelope protein, 1e. A fragment of a Ty element in yeast, 1f. A copia element in insect, 1g. A copia-like element in insect, 1h. A VL30 in mice and 1i. A IAP gene in mice.
 - E. The envelope or capsid protein should be elected from: 2a. A retrovirus, 2b. A piconavirus, 2c. A reovirus, 2d. A polymavirus, 2e. A papillomavirus, 2f. A parvovirus, 2g. A nodavirus, 2h. A coronavirus, 2i. A herpesvirus, 2j. A hepadnavirus, 2k. baculovirus and 2l. bacteriophage.
 - F. The substance should be elected from: 3a. proteins, 3b. poly or oligonucleotides, 3c. organic molecules of lower molecule weight and ions.
-
- IV. Claim 138, drawn to use of a viral like particle (VLP) for treatment of diseases, classified in class 435, subclass 472.
 - V. Claim 139, drawn to a use of a VLP to identification and characterization of interaction between target molecules and VLP, classified in class 424, subclass 5.
 - VI. Claim 140, drawn to a use of a VLP to identify a target molecule, classified in class 435, subclass 7.2.
 - VII. Claim 141, drawn to a use of a VLP to identify a potential pharmaceutical active substances, classified in class 435, subclass 7.8.

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VIII. Claim 142, drawn to a use of a VLP to identify diagnostic applications, classified in class 435, subclass 7.72.

IX. Claims 143-157, drawn to a method for identifying a compound that modulates a cell surface protein-mediated activity, classified in class 435, subclass in 7.21.

The groups IX is directed to the following patentably distinct species. If group IX is elected, Applicants are further required to selected one of the following species:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 143 is generic.

- A. The second amino acid sequence of target molecule should be selected from: a. A receptor, b. A iron channels, c. An enzymes, d. An adhesion molecule, e. A component of membrane pore and f) A luminescent peptide or protein.
- B. The second amino acid sequence of signal molecule should be selected from: 1a. A viral capsid protein, 1b. A precursor of a viral capsid protein, 1c. A fragment of envelope protein, 1d. A precursor of a viral envelope protein, 1e. A fragment of a Ty element in yeast, 1f. A copia element in insect, 1g. A copia-like element in insect, 1h. A VL30 in mice and 1i. A IAP gene in mice.
- C. The envelope or capsid protein should be elected from: 2a. A retrovirus, 2b. A piconavirus, 2c. A reovirus, 2d. A polymavirus, 2e. A papillomavirus, 2f. A parvovirus, 2g. A nodavirus, 2h. A coronavirus, 2i. A herpesvirus, 2j. A hepadnavirus, 2k. baculovirus and 2l. bacteriophage.
- D. The transcriptional control region should be elected from: a. serum response elements, b. cycline adenosine monphosphate response element, and c. element responsive to intracellular calcium ion level.

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- X. Claims 158-161, drawn to a recombinant cell comprising a DNA encoding a cell surface protein modulatable by an extracellular signal, classified in class 435, subclass 70.1.

The group X is directed to the following patentably distinct species. If any one of groups from I-III is elected, Applicants are further required to select one of the following species:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 158 is generic.

- A. The second amino acid sequence of target molecule should be selected from: a. A receptor, b. A ion channels, c. An enzymes, d. An adhesion molecule, e. A component of membrane pore and f) A luminescent peptide or protein.
- B. The transcriptional control region should be elected from: a. serum response elements, b. cyclin adenosine monophosphate response element, and c. element responsive to intracellular calcium ion level.

- XI. Claims 162-169, drawn to an assay for screening a compound, classified in class 435, subclass 7.91.

- XII. Claims 170-176, drawn to an assay for screening a plurality of compounds to determine the degree of inhibition or stimulation of an interaction between two target molecules, classified in class 435, subclass 960.

- XIII. Claims 177-182, drawn to an assay for determining the intracellular protein-protein interactions, classified in class 435, subclass 7.7.

- XIV. Claims 183-193, drawn to an assay for identifying a nucleic acid sequence, classified in class 435, subclass 91.1.

The group XIV is directed to the following patentably distinct species. If Group XIV is elected, Applicants are further required to select one of the following species:

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 183 is generic.

- A. The second amino acid sequence of target molecule should be selected from: a. A receptor, b. A iron channels, c. An enzymes, d. An adhesion molecule, e. A component of membrane pore and f) A luminescent peptide or protein.

XV. Claims 194-197, drawn to a method for identifying a substance associated with cell membrane, classified in class 434, subclass 7.8.

The group XV is directed to the following patentably distinct species. If group XV is elected, Applicants are further required to selected one of the following species:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 194 is generic.

- A. The second amino acid sequence of target molecule should be selected from: a. A receptor, b. A iron channels, c. An enzymes, d. An adhesion molecule, e. A component of membrane pore and f) A luminescent peptide or protein.
- B. The nucleic acid molecule should be elected from: 4a. A genomic DNA, 4b. cDNA, 4c. A mRNA, 4d. An antisense sequence, and 4e. A vector.

XVI. Claims 198-200, drawn to cell lines classified in class 435, subclass 325.

The group XVI is directed to the following patentably distinct species. If Group XVI is elected, Applicants are further required to selected one of the following species:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 198 is generic.

- A. The DNA molecule should be elected from: 1. A receptor, 2. A membrane pore, and 3. An iron channel.

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- B. The transcriptional control region should be elected from: a. serum response elements, b. cycline adenosine monphosphate response element, and c. element responsive to intracellular calcium ion level.

XVII. Claims 201-212, drawn to a method for identifying substance, which modulate signaling pathway classified in class 435 subclass 7.21.

The group XVII is directed to the following patentably distinct species. If Group XVII is elected, Applicants are further required to selected one of the following species:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 201 is generic.

- A. The mechanism for using the first amino acid to make the product should be selected from: 1. Van der Waals forces, 2. Electrostatic forces, 3. Stacking interactions, 4. Hydrogen bonding, and 5. Steric fit.
- B. The mechanism for releasing the viral like particle should be selected from: i. Exocytosis, ii. Lysis and iii. budding through the membrane.
- C. The second amino acid sequence of target molecule should be selected from: a. A receptor, b. A iron channels, c. An enzymes, d. An adhesion molecule, e. A component of membrane pore and f) A luminescent peptide or protein.
- D. The second amino acid sequence of signal molecule should be selected from: 1a. A viral capsid protein, 1b. A precursor of a viral capsid protein, 1c. A fragment of envelope protein, 1d. A precursor of a viral envelope protein, 1e. A fragment of a Ty element in yeast, 1f. A copia element in insect, 1g. A copia-like element in insect, 1h. A VL30 in mice and 1i. A IAP gene in mice.
- E. The envelope or capsid protein should be elected from: 2a. A retrovirus, 2b. A piconavirus, 2c. A reovirus, 2d. A polymavirus, 2e. A papillomavirus, 2f. A parvovirus, 2g. A nodavirus, 2h. A coronavirus, 2i. A herpesvirus, 2j. A hepadnavirus, 2k. baculovirus and 2l. bacteriophage.

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- F. The complex should be elected from 3a. A homo-dimer, 3b. A hetero-dimer, 3c. A homo-oligomer and 3d. hetero-oligomer.
- G. The nucleic acid molecule should be elected from: 4a. A genomic DNA, 4b. cDNA, 4c. A mRNA, 4d. An antisense sequence, and 4e. A vector.

XVIII. Claims 213-231, drawn to a method for making a VLP, and the VLP, classified in class 435, subclass 263.

The group XVIII is directed to the following patentably distinct species. If Group XVIII is elected, Applicants are further required to select one of the following species:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 213 is generic.

- A. The mechanism for using the first amino acid to make the product should be selected from: 1. Van der Waals forces, 2. Electrostatic forces, 3. Stacking interactions, 4. Hydrogen bonding, and 5. Steric fit.
- B. The mechanism for releasing the viral like particle should be selected from: i. Exocytosis, ii. Lysis and iii. budding through the membrane.
- C. The second amino acid sequence of target molecule should be selected from: a. A receptor, b. A ion channels, c. An enzymes, d. An adhesion molecule, e. A component of membrane pore and f) A luminescent peptide or protein.
- D. The second amino acid sequence of signal molecule should be selected from: 1a. A viral capsid protein, 1b. A precursor of a viral capsid protein, 1c. A fragment of envelope protein, 1d. A precursor of a viral envelope protein, 1e. A fragment of a Ty element in yeast, 1f. A copia element in insect, 1g. A copia-like element in insect, 1h. A VL30 in mice and 1i. A IAP gene in mice.

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- E. The envelope or capsid protein should be elected from: 2a. A retrovirus, 2b. A piconavirus, 2c. A reovirus, 2d. A polymavirus, 2e. A papillomavirus, 2f. A parvovirus, 2g. A nodavirus, 2h. A coronavirus, 2i. A herpesvirus, 2j. A hepadnavirus, 2k. baculovirus and 2l. bacteriophage.
- F. The substance should be elected from 3a. A protein, 3b. A poly or oligonucleotides, 3c. An organic molecule of lower molecule weight and 3d.. An ion.
- G. The nucleic acid molecule should be elected from: 4a. A genomic DNA, 4b. cDNA, 4c. A mRNA, 4d. An antisense sequence, and 4e. A vector.
- H. The transcriptional control region should be elected from: a. serum response elements, b. cycline adenosine monphosphate response element, and c. element responsive to intracellular calcium ion level.
- XIX. Claim 232, drawn to a reagent kit, classified in 435, subclass 975.
- XX. Claim 233, drawn to a medicament, classified in 424, subclass 93.6.
- XXI. Claim 234, drawn to a method for using the VLP for concentration, isolation and purification of a recombinant molecule, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, X, XVI, XIX and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to the compositions comprising structural different products, which use differently, i.e. the product of Group III is used for the treatment, whereas the product of Group XVI is used for making a viral like particle.

Inventions IV, V, VII-IX, XI-XV, XVII-XVIII and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to the functional different

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methods i.e. the method of Group VII is used for identifying a pharmaceutically active substance, whereas the method of Group VIII is used for the diagnosis.

Inventions VIII and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of diagnosis as claimed can be practiced with material different product, such as nucleotides, rather than viral like particle, whereas the product as claimed can be used for material different process, such as gene delivery rather than diagnosis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for one of the Groups are not required for another one of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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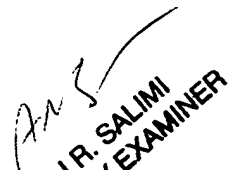
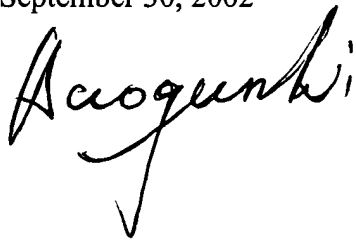
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

September 30, 2002



ALI R. SALIMI
PRIMARY EXAMINER